Health Information Technology Advisory Committee™

The Office of the National Coordinator for Health Information Technology

Meeting Notes

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC)

April 15, 2021, 10:30 a.m. – 2:30 p.m. ET

VIRTUAL

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EXECUTIVE SUMMARY

The co-chairs of the HITAC, **Denise Webb** and **Aaron Miri**, welcomed members, reviewed the meeting agenda, and the minutes from the March 10, 2021 HITAC meeting, which were approved by voice vote. **Micky Tripathi** welcomed members and discussed COVID-19 pandemic response efforts and other non-COVID-related work currently underway at ONC. **Steven Lane** and **Leslie Kelly Hall** presented recommendations to the HITAC from the United States Core Data for Interoperability (USCDI) Task Force (TF) 2021 (USCDI TF 2021). HITAC members unanimously approved the USCDI TF 2021's recommendations by a voice vote. **Tim Noonan,** Deputy Director for Health Information Privacy, HHS Office for Civil Rights (OCR), gave a presentation on OCR's proposed modifications to the HIPAA Privacy Rule. **Arien Malec** and **David McCallie** provided an update on the recent work of the Interoperability Standards Priorities (ISP) Task Force (TF) (ISP TF 2021). **Micky** announced the formation of the new Public Health Data Systems Task Force and provided a brief overview of its charge and goals. HITAC members discussed the presentations and submitted feedback and questions. One public comment was submitted by phone, and there was a robust discussion in the public meeting chat via Adobe.

AGENDA

10:30 a.m.	Call to Order/Roll Call
10:35 a.m.	Welcome Remarks
10:45 a.m.	Remarks, Review of Agenda and Approval of March 10, 2021 Meeting Minutes
10:55 a.m.	United States Core Data for Interoperability Task Force 2021 (USCDI TF 2021) – Recommendations on Version 2 of the USCDI (USCDI v2) & HITAC Vote
11:55 a.m.	Proposed Modifications to the HIPAA Privacy Rule to Support and Remove Barriers to Coordinated Care and Individual Engagement
12:55 p.m.	Break
01:05 p.m.	Interoperability Standards Priorities (ISP) Task Force Update
01:55 p.m.	Public Health Data Systems
02:15 p.m.	Public Comment
02:30 p.m.	Final Remarks and Adjourn

CALL TO ORDER/ ROLL CALL

Mike Berry, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC), called the April 15, 2021, meeting to order at 10:30 a.m.

Jim Jirjis disclosed a potential conflict of interest: HCA Healthcare was approached to consider participating in a pilot program with HASA (in Texas), and one of HCA's chief medical informatics officers (CMIO) is on the board for HASA. There is no signed relationship at this time, but they are considering the offer.

ROLL CALL

Aaron Miri, The University of Texas at Austin, Dell Medical School and UT Health Austin, Co-Chair
Denise Webb, Indiana Hemophilia and Thrombosis Center, Co-Chair
Michael Adcock, Magnolia Health
Cynthia A. Fisher, PatientRightsAdvocate.org
Lisa Frey, St. Elizabeth Healthcare
Steven Hester, Norton Healthcare
Jim Jirjis**,** HCA Healthcare
John Kansky, Indiana Health Information Exchange
Kensaku Kawamoto, University of Utah Health
Steven Lane, Sutter Health
Leslie Lenert, Medical University of South Carolina
Arien Malec, Change Healthcare

Clem McDonald, National Library of Medicine
Brett Oliver, Baptist Health
Terrence O'Malley, Individual
Carolyn Petersen, Individual
Raj Ratwani, MedStar Health
Abby Sears, OCHIN
Alexis Snyder, Individual
Sasha TerMaat, Epic
Andrew Truscott, Accenture
Sheryl Turney, Anthem, Inc.
Robert Wah, Individual

MEMBERS NOT IN ATTENDANCE

Valerie Grey, New York eHealth Collaborative
James Pantelas, Individual

FEDERAL REPRESENTATIVES

Amy Abernethy, Food and Drug Administration
James Ellzy, Defense Health Agency, Department of Defense
Adi V. Gundlapalli, Centers for Disease Control and Prevention
Jonathan Nebeker, Department of Veterans Health Affairs
Michelle Schreiber, Centers for Medicare and Medicaid Services
Ram Sriram, National Institute of Standards and Technology

ONC STAFF

Micky Tripathi, National Coordinator for Health Information Technology
Steve Posnack, Deputy National Coordinator for Health Information Technology
Elise Sweeney Anthony, Executive Director, Office of Policy
Avinash Shanbhag, Acting Executive Director, Office of Technology
Michael Berry, Designated Federal Officer
Michelle Murray, Staff Lead

PRESENTERS

Leslie Kelly Hall, Engaging Patient Strategy, USCDI TF 2021 Co-Chair
David McCallie, Individual, ISP TF 2021 Co-Chair
Tim Noonan, Deputy Director for Health Information Privacy, HHS Office for Civil Rights (OCR)

WELCOME REMARKS

Micky Tripathi, the National Coordinator for Health IT, welcomed everyone to the April 15, 2021, virtual meeting of the HITAC. He provided an overview of ONC's recent involvement with the healthcare industry on COVID-19 pandemic response efforts, which included work to improve the vaccine appointment scheduling experience through a Fast Healthcare Interoperability Resources-based (FHIR) approach. ONC will host an arrangement to test the implementation of the FHIR-based platform with a coalition of partners who want to move forward in a standards-based way. Additionally, ONC and the Centers for Disease Control and Prevention (CDC) are co-leading work related to an executive order on how public health data systems aid in public health emergencies. He announced that the HITAC will hold a hearing on public health topics on May 13, 2021, in conjunction with its regularly scheduled meeting. Also, the HITAC will sponsor a Public Health Data Systems Task Force, which will have its kick-off meeting in early May 2021.

Micky explained that non-COVID-19 related efforts underway have included hosting ONC's Annual Meeting and preparation for the arrival of the applicability date for ONC's Information Blocking Final

3

Rule (on April 5, 2021), which included outreach to support all stakeholders and industry partners. **Micky** and **Steve Posnack** co-authored a blog post on the implementation of the Final Rule at: https://www.healthit.gov/buzz-blog/information-blocking/a-new-day-for-interoperability-the-information-blocking-regulations-start-now Additionally, he directed members to an update of the Certified Health IT section of ONC's Health IT Playbook, which was released here: https://www.healthit.gov/playbook/ He announced that the HITAC Annual Report for Fiscal Year 2020 (FY20) was sent to the Secretary of HHS and to Congress, and he thanked the Annual Report Workgroup (AR WG) for their efforts.

Micky thanked **Amy Abernethy** for her service and contributions to the HITAC. She will be leaving her position as the Principal Deputy of the Commissioner and CIO of the FDA within the month, so she will no longer be able to represent the FDA to the HITAC.

REMARKS, REVIEW OF AGENDA, AND APPROVAL OF MARCH 10, 2021 MEETING MINUTES

Aaron Miri and **Denise Webb**, HITAC co-chairs, welcomed members. **Aaron** reminded members that the deadline for compliance with the information blocking provision of the 21st Century Cures Act (Cures Act) was April 5, 2021. He shared two anecdotes about patients to emphasize that the public is aware of their new right to request and be provided with their information immediately.

Denise stated that she was looking forward to the lively discussions that would follow the presentations made to the HITAC at the current meeting and reminded members that she and **Aaron** have both participated in the USCDI Task Force. She added that stakeholder groups from across the healthcare industry have been very engaged with the work of the HITAC's various task forces.

Denise welcomed **Steven Hester** from Norton Healthcare in Kentucky, who is a new member of the HITAC, and **Steven** introduced himself. He is looking forward to contributing his perspective as a provider. **Aaron** thanked Steven for his work on the frontlines of the COVID-10 pandemic.

Aaron briefly reviewed the agenda, and **Denise** invited members to examine the minutes from the March 10, 2021, meeting of the HITAC. Members of the HITAC submitted no comments or corrections, so she called for a motion to approve the minutes. **Steven Lane** made a motion, which **Andy Truscott** seconded. The HITAC approved the March 10, 2021, meeting minutes by voice vote. No members opposed, and no members abstained.

UNITED STATES CORE DATA FOR INTEROPERABILITY TASK FORCE 2021 (USCDI TF 2021) – RECOMMENDATIONS ON USCDI V2 & HITAC VOTE

Steven Lane and **Leslie Kelly Hall**, co-chairs of the USCDI TF 2021, presented the TF's recommendations on the draft of version 2 of the USCDI (USCDI v2). **Leslie** provided an overview of the USCDI TF 2021 membership and discussed the TF's overarching and specific charges. In recent meetings, the TF has focused on Tasks 1a, 1b, and 1c of Charge 1, which included:

- Charge 1: Evaluate Draft USCDI v2 and provide HITAC with recommendations for:
  - Task 1a - Data classes and elements from USCDI v1 including applicable standards version updates
  - Task 1b - New data classes and elements from Draft USCDI v2 including applicable standards
  - Task 1c - Level 2 data classes and elements not included in Draft USCDI v2

Now that Charge 1 work has been completed, **Leslie** explained that the USCDI TF 2021 will begin to focus on Charges 2 and 3, which are due by September 9, 2021, and included:

- Charge 2: Evaluate the USCDI expansion process and provide HITAC with recommendations for:
    - o Task 2a- ONDEC submission system improvements
    - o Task 2b - Evaluation criteria and process used to assign levels to submitted data classes and elements
    - o Task 2c - Prioritization process used by ONC to select new data classes and elements for Draft USCDI v2
- Charge 3: Recommend ONC priorities for USCDI version 3 (USCDI v3) submission cycle

Leslie directed HITAC members to an updated representation of draft USCDI v2 in the presentation slides and explained that new data classes and elements were added since USCDI v1. She discussed the USCDI TF 2021's work process on these items.

Steven thanked **Leslie** for stepping into the role as co-chair and noted her efforts to represent the patient perspective on the USCDI TF 2021. He discussed the TF's recent meeting schedule, work, and discussions. The TF's report was shared with the HITAC, and Steven noted that they made an effort to keep it focused and brief. Both co-chairs emphasized that the TF's conversations ranged beyond the scope with which it was charged, but the scope restricted its recommendations.

Steven reviewed the draft USCDI v2 and a timeline depicting ONC's cyclical process to advance the USCDI. All of these items were detailed in the TF's presentation slides. He explained that the TF has decided to present to the HITAC two more times in 2021 (summer and at the HITAC's September meeting), so he emphasized that this is not the final discussion on expanding the USCDI. He provided background on the process used by the USCDI TF, ONC, and the HITAC to advance the USCDI. Then, he summarized and provided background details on the USCDI TF 2021's recommendations to the HITAC, which were covered in the presentation slides, and included:

- Recommendations to support Charge 1, Task 1a:
    - o Clarify the need for both the Assessment and Plan of Treatment data class and data element, separately
    - o Clarify scope or limits of imaging study types (only radiology, or includes visible light photographic or video images, e.g., from endoscopic studies) for the Diagnostic Imaging Order data element, which is under the Diagnostic Imaging data class
    - o Clarify scope and definition to distinguish the Test data element, which is under the Laboratory data class, from Diagnostic Studies/Exams
    - o Add Unified Code for Units of Measure (UCUM) as applicable standard for the Values/Results data element under the Laboratory data class, as it is widely used
    - o Add ICD-10 as applicable standard (allowed), for the Problems data element/data class, as ICD-10 is commonly used to represent problems in a list. This is in addition to SNOMED, which was already included in USCDI v1.
    - o A set of recommendations around the Procedures data class/data element included:
        - ▪ Clarify definition and scope of procedures, whether it includes diagnostic and therapeutic procedures.
        - ▪ Differentiate between diagnostic studies and procedures
- Recommendations to support Charge 1, Task 1b:
    - o The Provider Identifier data element, under the Care Team Members data class, should include identifier code system (i.e., NPI) and version. The TF did not specify the particular code to be used.

- o Change Provider Name and Provider Identifier data elements to Care Team Member Name and Identifier. Data elements pertain to all care team members, including non-providers and family caregivers.
- o Support the new Diagnostic Imaging Narrative data element, which was reclassified from Clinical Notes to the Diagnostic Imaging data class but clarify definition and scope to require both structured and unstructured/narrative components.
- o Specifically reference the coded billing diagnoses for encounters in the Encounter diagnosis data element under the Encounter Information data class.
- o Clarify scope and definitions of timing element(s) and provide examples for the Encounter Time data element under the Encounter Information data class (e.g., scheduled start/stop time, scheduled/arrival time, admission/discharge time). The duration of encounters is utilized in CMS electronic clinical quality measures (eQCMs) and is beneficial for workflow management. The TF did not clarify the specific definitions.
- o Remove Laboratory and Pathology Report Narratives as distinct data elements under the Laboratory data class but ensure that they are included in the definition of the report, as the TF decided there was questionable value of stand-alone Narrative elements without the context of a whole report.
- o Support the Values/Result data element (under the Laboratory data class) but clarify definition and scope of Value/Result to require both structured and unstructured/narrative components. This aligns with the Laboratory Value/Result containing structured and unstructured (narrative) content.
- Recommendations to support Charge 1, Task 1c:
  - o Add the following Level 2 data elements to USCDI v2 under the Care Team Members data class and change names from "Provider" to "Care Team":
    - ▪ Provider Role
    - ▪ Provider Location
    - ▪ Provider Telecom Information
    - ▪ Provider NPI
    - ▪ Provider DEA Number
  - o Add the data elements for diagnostic studies and exams with results to the USCDI v2 under the Diagnostic Studies/Exams data class and clarify the scope and definitions for diagnostic study types or categories including (without images):
    - ▪ Colonoscopy
    - ▪ Echocardiogram
    - ▪ Electrocardiogram
    - ▪ Pulmonary Function Tests
  - o A set of recommendations for the Encounter Disposition data element under the Encounter Information data class included:
    - ▪ Add data element, applicable to at least hospital, short stay and emergency department (ED) encounters and long-term care, when possible
    - ▪ Applicable standard: HL7 Discharge Disposition code system
  - o Add the Encounter Location data element to USCDI v2 under Encounter Information and specify to include or allow TIN/CCN as location identifiers.

- o   Add the Medication data class under the Discharge Medications data class, contingent on inclusion in HL7® US Core and C-CDA Implementation Guides, because the distinction of discharge medications is key to safe transitions of care, coordination of care, and patient / caregiver engagement.
- o   Add the types of order for medical care/services data elements under the Orders data class and specify that orders for end-of-life care (palliative, hospice, comfort care) be included in certification testing
- o   Add the Gender Identity and Sexual Orientation data elements under Patient Demographics, contingent on inclusion in HL7® US Core and C-CDA Implementation Guides. Gender identity and sexual orientation data are fundamental to patient safety, equity and care.
- o   Add the Medicare Beneficiary ID (MBI) data element under Patient Demographics, contingent on inclusion in HL7® US Core and C-CDA Implementation Guides, as MBI is readily available and required for billing, advances, and linkage between billing and electronic health records (EHRs)
- o   Add the following Level 2 data elements under the Social Determinants of Health (SDOH) data class and request ONC to prioritize the relevant IGs for finalization as a prerequisite to adding these data elements to USCDI:
  - ▪ Assessment
  - ▪ Problems/Health Concerns
  - ▪ Interventions
  - ▪ Goals
  - ▪ Outcomes

Steven explained that the USCDI TF 2021's preliminary suggestions to the HITAC for consideration for USCDI v3 were included in the presentation slides. The TF will present its finalized recommendations to the HITAC at a future meeting, but TF members have already had robust discussions around USCDI v3 topics.

Leslie discussed the USCDI TF 2021's remaining Phase 2 work on Charges 2 and 3, and a summary was included in the presentation slides. **Leslie** summarized the areas where further HITAC guidance is needed, including discussions around the scope and alignment of USCDI regulatory efforts and stakeholder needs. She invited HITAC members to provide feedback on a process for prioritizing stakeholder input and needs and highlighted the lack of sponsorship for the needs of "data underserved" populations.

USCDI TF 2021 Phase 2 scheduled meeting dates were listed in the presentation slides. The co-chairs invited HITAC members to submit feedback and comments on the TF's recommendations and presentation.

Discussion:

- ● **Abby Sears** thanked the presenters and the USCDI TF 2021 for their hard work and, in response to a question from the TF's co-chairs about data for the underserved, explained that one of her major roles on the HITAC is to represent these populations. She discussed recent public health data challenges related to SDOH and described examples of issues with data capture, data management, and administrative burdens. She highlighted issues the patient population is currently facing (mental health, chronic disease) that make care coordination more challenging and care more costly. She stated that standardizing SDOH data in the United States would better serve at-risk populations and provide greater health equity and encouraged the TF to move as many SDOH data elements forward as possible.

- o **Steven** thanked **Abby** and added that her statements about the critical nature of SDOH data reflected conversations held by the USCDI TF 2021. Because ONC labeled five data elements as Level 2, these were the only eligible elements within their work scope. The TF determined that it was critical to have the implementation guides that support the elements finalized first.
- **Michelle Schreiber** thanked the TF co-chairs for considering many recommendations submitted by CMS. She discussed the rationale behind their recommendations (eQCMs, etc.), noting her support for SDOH elements, but stated that ONC should step back and consider the ultimate goal for the USCDI. She suggested that they should hold a discussion to come up with a philosophical approach and agreement.
  - o **Steven** thanked CMS for playing an active role in the TF's work, noting that some of the suggestions CMS made were included in the TF's final recommendations to the HITAC. CMS will provide additional detail on other recommendations, which will be shared again in the future.
  - o **Leslie** echoed **Steven's** comments and stated that the TF and CMS weighed the issues of care, regulatory need, and patient advocacy during their discussions.
  - o **Aaron** noted his support for the emphasis on SDOH.
- **Steve Posnack** thanked everyone for their contributions and asked TF members to discuss Recommendation #5. He suggested that it is inconsistent with standards policy that has been in place since 2021, which stated that SNOMED Clinical Terms (SNOMED CT) would be the single coding system used for clinical problems.
  - o **Steven** responded that, though SNOMED CT is detailed, helpful, and meets system goals, problems are currently captured as diagnoses, then billed and added to the problems list. Due to changes in the process, many systems have to take ICD-10 coded diagnoses, map them to SNOMED, and then map them back to ICD-10. He stated that allowing for the inclusion of ICD-10, in addition to SNOMED, reduces burdens related to mapping.
  - o **Leslie** stated that there should be a continuum that goes from the problem all the way to a bill, so all medical records are easier for a patient to decipher. Also, by using ICD-10, there is a way to better track, review, and analyze the data for quality measurements and internal process reviews.
- **Aaron** highlighted several comments from the public chat and expanded on one from **Jonathan Nebeker** about how USCDI fits into the larger picture of healthcare and interoperability. He stated that the USCDI is a framework to which certified health IT vendors are certified against, and continued work by the USCDI TF 2021 will clarify questions about the USCDI and its expansion process.
  - o **Steven** explained that the TF plans to develop a set of guiding principles that will be applied going forward. He invited the HITAC to weigh in on recommendations for future versions of the USCDI and guiding principles.
  - o **Jonathan** suggested that they coordinate with CMS to take advantage of a more mature and usable set of data due to terminological advancements and implementations, and to examine the regulatory framework. Questions could include, "Where does the USCDI fit in the framework?" and "What is the USCDI's role in advancing the connectedness of knowledge networks for more usable and more ontologically reasonable data."
  - o **Leslie** responded that the TF has begun to discuss this topic and emphasized the continuity of information/connectedness in a knowledge network. Therefore, the TF has recommended adding ICD-10, when available, to promote the continuity of information.
  - o **Steven** responded that ICD-10 was included because some systems use it to codify diagnoses for billing and orders and often use the same diagnoses on the problem list.

- **Clem** suggested that ICD-11 might be more useful than ICD-10 and described other vocabularies (HPL, etc.) that are used in research areas, like genetics. He stated that both ICD-10 and SNOMED should be allowed for now.
  - o **Steven** thanked **Clem** for his comment and asked him to share his suggestion for a data element that goes beyond the scope the TF was given.
  - o **Clem** explained that he had suggested including tonometry (intended to protect against glaucoma and reduce blindness) as a data element, but the TF did not think there was an electronic transfer of tonometry. However, they discovered that the American Academy of Ophthalmology recorded interocular pressure for millions of patients.
  - o **Steven** clarified that Clem's argument was that tonometry was mis-leveled by ONC (as Level 1, which would be out of scope for the TF), and it should be a Level 2 data element. Then, it could be included in the TF's #15 recommendation along with the other diagnostic studies and exams.
  - o **Clem** and **Steven** disagreed if it was within the TF's scope to make a recommendation about tonometry.
- **Andy Truscott** agreed that ICD-10 should be included along with SNOMED in that particular recommendation but emphasized that the use of SNOMED should be encouraged while the use of ICD is temporary. Also, he voiced his support for Clem's comments. He cautioned that the USCDI should be the "core" of data elements and not just useful items but not necessarily within the core data.
  - o **Steven** thanked **Andy** for his participation in the TF and willingness to take on extra work.

Aaron Miri made a motion to approve the recommendations of the USCDI TF 2021, which Andy Truscott seconded.

The HITAC approved the recommendations of the USCDI TF 2021 by voice vote. No members opposed, and no members abstained.

Steven and **Leslie** discussed the TF's next steps, which include focusing on Charges 2 and 3. The USCDI TF 2021 would like to proceed with Charge 3 first to provide input to ONC for the prioritization process they will use to evaluate USCDI v3 submissions. The co-chairs directed HITAC members to the list of upcoming TF meetings in the presentation slides. **Leslie** stated that the TF plans to look at broader classes of service during its future work instead of using a more piecemeal approach.

Denise reminded HITAC members that, now that they have voted and approved the USCDI TF 2021's recommendations, the HITAC will be advancing the letter to the National Coordinator and request that he endorses those recommendations.

PROPOSED MODIFICATIONS TO THE HIPAA PRIVACY RULE TO SUPPORT, AND REMOVE BARRIERS TO, COORDINATED CARE AND INDIVIDUAL ENGAGEMENT

Tim Noonan, Deputy Director for Health Information Privacy, HHS Office for Civil Rights (OCR), introduced himself and gave a brief overview of the agenda for his presentation on OCR's proposed modifications to the HIPAA Privacy Rule. He stated that OCR is the federal agency responsible for administering and enforcing the HIPAA Rules, which they do through rulemaking and guidance, investigations, and enforcement actions and outreach.

Tim informed HITAC members that there was a link to OCR's notice of public rulemaking (NPRM) in the presentation materials and added that the public comment period is open through May 6, 2021, during

which they are soliciting public comments on proposals to modify the HIPAA Privacy Rule to improve health information sharing for more effective healthcare, to empower individuals with their own health information, and to list unnecessary burdens on covered healthcare providers and health plans. He provided background information on the process, including a request for information that garnered over 1,300 comments that spanned almost 4,000 pages. OCR reviewed and evaluated all of them.

Tim stated that OCR's NPRM had eight topical sections, which included:

- Right of Access
- Notice of Privacy Practices
- Disclosures of Protected Health Information (PHI) in the Best Interests of Individuals
- Disclosures to Lessen or Prevent Threat of Harm
- Care Coordination and Exception to Minimum Necessary Standard
- Disclosures to Facilitate Care with Social and Community Services
- Telecommunication Relay Services
- Uniformed Services

Tim explained that the Individual Right of Access section and proposals were the largest section of the NPRM, so they would be the bulk of the presentation's focus. He shared an overview of the Right of Access Proposals, which included:

- New defined terms
- Shorter response timelines for access requests
- Transmitting PHI to a personal health application
- Preventing unreasonable measures for access and identity verification
- Viewing and capturing images of PHI
- Directing copies to a third party
- Individual-directed information sharing among covered providers and plans
- Fee limitations
- Posting fee schedules

Tim stated that the Health Information Technology for Economic and Clinical Health (HITECH) Act included a definition of an electronic health record (EHR), so OCR proposed to add it to HIPAA, along with definitions for other previously undefined terms ("clinicians," "health-related information on an individual," and "personal health application"). He discussed the proposed definitions and justification for changes and explained that the new definitions used terms that are already defined within HIPAA and the HITECH Act. These definitions were included on slides #4 and #5 in the presentation.

Tim explained that because more individuals are using health apps to access and manage their information, OCR has proposed to revise the Right of Access, which can be fulfilled through the transfer of electronic information via an individual's personal use of a health app. According to the new definition, "personal health application" means an electronic application used by an individual to access health information about that individual, which can be drawn from multiple sources, provided that such information is managed, shared, and controlled by or primarily for the individual, and not by or primarily for a covered entity or another party such as the application developer. He explained that the personal health app would be seen as a service offered to consumers and would not act on behalf of/at the direction of the covered entity. Therefore, they would not be a HIPAA business associate or be subject to the privacy and security obligations of HIPAA Rules. He stated that this would reduce confusion and give individuals the ability to make better use of their right to access health information.

Tim discussed how shortening response timelines for covered entities to act upon access requests (from 30 days, with the possibility of a 30-day extension, to 15 days, with a 15-day extension) will strengthen

individuals' rights to access their health information and enhance care coordination. Eight states in the U.S. already have shortened right of access timeline requirements. He described work OCR has done on its Right of Access Enforcement Initiative to get covered entities to prioritize urgent/high priority requests. OCR proposed to modify the privacy rule to prohibit a covered entity from imposing unreasonable measures on an individual who is exercising their right. Therefore, a covered entity may require access requests in writing, but only if the covered entity informs the individual of the requirement and does not impose unreasonable measures impeding the individual from obtaining access when a less burdensome measure is practicable for the covered entity. He discussed several examples of some of the burdensome/unreasonable measures and noted that OCR has invited public comment on these proposals using specific questions on each section.

Tim explained that the HIPAA Privacy Rule requires a covered entity to verify the identity of a person who has requested protected health information, but OCR does not mandate a specific form of verification. They are clarifying that, while current identity verification requirements remain, unreasonable identity verification requirements for individuals attempting to exercise their rights under the HIPAA Rules will be prohibited. He stated that unreasonable measures cause an individual to expend unnecessary effort or resources when a less burdensome verification measure is practicable for the covered entity.

OCR is working to eliminate barriers they discovered in their enforcement program (including 28,000 HIPAA complaints a year), so **Tim** explained that OCR has proposed strengthening the Right to Inspect to reduce the number of Right of Access complaints received by OCR. This includes the right to view, to take notes and photographs, and to use other personal resources to capture PHI in a designated record set at a mutually convenient time and place, including in conjunction with a health care appointment. He stated that a covered entity may establish the following limits and discussed examples of each:

- Not required to allow connection of personal devices to covered entity's information systems
- May impose measures to ensure individual only records PHI to which individual has right of access
- May establish reasonable policies and safeguards to minimize disruption to operations

Tim explained that the HIPAA Privacy Rule requires the covered entity to provide an individual with access to their protected health information in the form and format requested, if readily producible in that form or format. OCR proposed that if other federal or state law requires an entity to implement a technology or policy that would have the effect of providing an individual with access to PHI in a particular electronic form or format then, such form and format would be deemed "readily producible." If a covered entity or its EHR developer (business associate) has implemented a secure, standards-based API that is capable of providing access to ePHI in the form and format used by an individual's personal health application, that ePHI is considered to be readily producible in that form and format

Tim discussed the implications of the decision in January 2020 in the Ciox Case for an individual's Right to Direct. He stated that a court held that an individual's right to direct a covered health care provider to transmit health records was limited to protected health information in an electronic health record to a third party in an electronic format (no longer allowed to direct paper health records). As a result, OCR proposed to revise the Right to Direct to be consistent with the Ciox decision; an individual would only have the right to direct a covered health care provider to transmit an electronic copy of PHI in an EHR to a third party using a "clear, conspicuous, and specific" request made orally or in writing (which may be electronically executed). The individual may use an internet-based method, such as a personal health application, to submit the access request, so long as it is "clear, conspicuous, and specific." He explained that some of the language was taken from the HITECH Act.

Tim explained OCR's proposal Right of Access to Direct Disclosures by describing example scenarios in which a patient's PHI is not shared between providers because it is permitted but not required to be shared. This can cause any number of complications, so OCR proposed that a requirement be created

within the Right of Access for a covered healthcare provider or health plan to facilitate an individual's request to direct electronic copy of PHI in an EHR to a third party (as designated by the individual). A graphic that illustrated this process was included on slide #12 in the presentation, and Tim used it to provide structure for an example in which an individual has a car accident in a state where they do not reside and receives a variety of treatments there. Under OCR's proposal, this individual/their family could ensure that all care providers in all states receive the appropriate electronic copies of their records. He explained that there would be five categories of allowable access requests and allowable fees (broken down by type of access and recipient), which were detailed in the presentation on slide #13. He provided examples for each allowable request/fee and cited ONC's Cures Act Final Rule and the HITECH Act. He explained that OCR has made this proposal and put it through the notice and comment process in compliance with the Administrative Procedures Act and reminded HITAC members that this is subject to the Right to Direct PHI to a third party, as previously discussed.

Tim explained that OCR proposed requiring covered entities to provide advance notice of the approximate fees for copies of PHI (requested under the access right and with an individual's valid authorization) to increase awareness of the cost of copies and to make the access fee requirements more uniform. He stated that OCR proposed that this information will be publicly available; covered entities will make it available via website posting and at point of service upon request. Types of access available and a fee schedule will be made available, and, upon the individual's request, the covered entity will provide an individualized estimate of approximate fees to be charged for copies and itemized list of charges for a specific request for copies. This will create transparency for the patient, bring covered entities into compliance, reduce the number of and time spent on OCR investigations.

Tim described the current Privacy Rule with regard to the Notice of Privacy Practices (NPP) and described OCR's proposals, which he stated would alleviate paperwork burdens and reduce confusion for patients and covered entities. These proposals included:

- Eliminate written acknowledgment requirements for the NPP
- Establish an individual right to discuss the NPP with a person designated by the covered entity
- NPP explains how to contact the designated person
- Make changes to NPP content to better inform individuals of their rights with respect to their PHI and how to exercise those rights. Modifications to the required header of the NPP include:
  - How to access their health information
  - How to file a HIPAA complaint
  - Right to receive a copy of the notice and to discuss its contents with a designated person

OCR believes that more can be done to encourage healthcare providers to disclose protected health information to family members/caregivers to assist with health-related emergencies. These disclosures of PHI should be done in the best interests of patients. OCR's proposals would permit disclosure of PHI based on good faith belief that disclosure is in the individual's best interests. He discussed the presumption of "good faith" and stated that the proposed good faith standard may be exercised by other workforce members who are trained on the covered entity's HIPAA policies and procedures and who are acting within the scope of their authority. **Tim** emphasized the importance of these proposals in light of the opioid crisis: a family might not know that a member is addicted or has had an emergency until it is too late.

Tim explained that OCR proposed to expand the ability of covered entities to disclose protected health information to avert a threat to health or safety when harm is "serious and reasonably foreseeable" instead of the current "serious and imminent" threat standard. He stated that this proposed modification would permit covered entities to make more timely disclosures of PHI without determining whether the threat or harm is imminent, which may not always be possible in some cases. He discussed an example

in which an emergency room doctor is treating an elderly patient with COVID-19 contacts the patient's nursing home to alert them of potential exposure.

OCR proposed to modify the definition of "healthcare operations," which encompasses all care coordination and case management by health plans, whether population-based or focused on particular individuals. The minor edit to the definition clarifies that health plans may use and disclose PHI for population-based *and individual* care coordination and case management under the permission to use and disclose PHI for health care operations. **Tim** described confusion around previous definitions of these terms and how this confusion has negatively affected care situations.

Also, **Tim** stated that the recognition that health plans conduct individual-level care coordination and case management supports OCR's next proposal to modify the minimum necessary standard to promote uses and disclosures for care coordination and case management for individuals. He explained that the minimum necessary requirements are based on the requirement that covered entities must limit their use, disclosure, or request for PHI to only the "minimum necessary to meet the purpose of the request." He discussed the reasoning behind this requirement and related barriers it imposes on care. OCR proposed the addition of an express exception to the minimum necessary standard for disclosures to, or requests by, a health plan or current healthcare provider for care coordination and case management for individuals. He explained that the exception would not apply to population-based care coordination and case management and that covered entities would still be able to honor individuals' requests for privacy restrictions.

Tim discussed the topic of Care Coordination Disclosures to Third Parties, noting that the current definitions already allow the disclosure of PHI from a healthcare provider for the coordination or management of healthcare. However, he stated that OCR has heard that this guidance is confusing to some. As a result, OCR proposed to clarify the definition so that express permission was given for covered entities to disclose PHI to third parties for care coordination and case management concerning an individual. These entities may include:

- Social services agencies
- Community-based organizations
- Home and community-based services providers (HCBS)
- Similar third parties that provide or coordinate health-related services

He stated that individuals can still request restrictions on disclosures of PHI for treatment, payment, and health care operations.

Tim explained that the Telecommunications Relay Service (TRS) is a federally mandated service that facilitates telephone calls between individuals who are deaf, hard of hearing, or deaf/blind and have a speech disability and others. Due to advances in technology, he explained that an individual may not be aware that TRS is being used, so OCR proposed to expressly permit disclosures to TRS communications assistants for persons who are deaf, hard of hearing, or deaf-blind, or who have a speech disability. This excludes TRS providers from the definition of "*business associate"* and ensures that workforce members of a covered entity or business associate can use TRS to share PHI with other workforce members or outside parties, as needed, to perform their duties.

The final OCR proposal allows the use and disclosure of PHI for uniformed services personnel. OCR proposed to extend permission to disclose PHI of Armed Forces personnel to include all uniformed services, adding the U.S. Public Health Service (USPHS) Commissioned Corps and the National Oceanic and Atmospheric Administration (NOAA) Commissioned Corps. **Tim** explained that the proposal allows disclosures necessary to assure the proper execution of the mission

In conclusion, Tim thanked the HITAC for the opportunity to present and provided contact information and additional resources, which were included at the end of the presentation slides.

Discussion:

- **Jim Jirjis** asked if OCR has considered adopting additional measures to ensure the privacy and security of health information as it travels to third parties (like personal health apps) outside of HIPPA protections. (Or are they limited by the Cures Act?)
  - o **Tim** responded OCR does not view itself as having direct authority over health apps offered directly to consumers through app stores. Congress discussed this topic recently, so he thinks that there might be a legislative solution underway. He suggested that the FTC could have limited jurisdiction, and OCR has worked with them in the past to alert them to issues. Greater legislative authority is needed before OCR can address the apps.
- **John Kansky** emphasized the need to continue to advance a channel for interoperability and for the patient to control the flow of their own information/PHI. This does not exist in the current ecosystem.
- **Aaron Miri** thanked **Tim** for the presentation and submitted several comments:
  - o He stated that he would hold many of his questions to formally respond to the NPRM.
  - o He requested that OCR put out a crosswalk that addressing differences between information blocking and OCR's proposals.
    - ▪ **Tim** responded that OCR and ONC could put together a final document that incorporates information blocking and right of access information.
  - o He asked if there would be a consideration for certified health IT vendors that intersect with covered entities and what responsibilities they would have to conform to OCR's proposed timelines.
    - ▪ **Tim** responded that OCR does not have direct authority over business associates (with respect to the right of access), so that is why they are focused on the covered entity (have authority over them) who is obligated to ensure timely action on a right of access request. However, when covered entities use business associates, challenges can occur. He described the nature of many of the right of access related complaints OCR received and the general process they take to resolve these cases. He explained that OCR tries to exercise discretion in its enforcement activities and to communicate directly with the covered entity, where they have clear jurisdiction and obligation.
- **Denise Webb** thanked **Tim** for the presentation and reminded HITAC members that the OCR presentation was informational. If they would like to make recommendations, they were encouraged to do so through the public comment process.

INTEROPERABILITY STANDARDS PRIORITIES (ISP) TASK FORCE UPDATE

Arien Malec and **David McCallie**, the Interoperability Standards Priorities Task Force 2021 (ISP TF 2021) co-chairs, introduced themselves. **Arien** thanked the HITAC for the opportunity to present and provided a brief overview of the ISP TF's roster and discussed the mission and charge of the ISP TF 2021, which is grounded in the 21st Century Cures Act (the Cures Act). Details of these items were included in the presentation slides.

Arien explained that the focus of the ISP TF 2021 was to identify opportunities to update the ONC Interoperability Standards Advisory (ISA). He provided an overview of the areas of potential interest that the TF identified, which included:

- Clinical/Administrative Data & Standards Harmonization/Burden Reduction

- o Specific standards actions related to recommendations from the Intersection of Clinical and Administrative Data Task Force, The Da Vinci Project, Fast FHIR, etc.
- Data sharing between Federal & Commercial Health Care Entities
  - o Address barriers to interoperability data flows that cross from Federal to/from Commercial
- Vaccine/Immunization Registry Reporting
  - o Lessons learned from COVID-19 pandemic on gaps in vaccine registry data flows
- Health Equity Standards
  - o Improved structure and capture for Race/Ethnicity/Gender and Social Determinants of Health
- Real-World Evidence (RWE)/Comparative Effectiveness/RECOVERY-type data use (from EHRs)
  - o Better leverage EHRs and EHR data for (rapid) hypothesis generation and testing
- Public Health (PH) Situational Awareness
  - o Improve standards and structures for reporting on real-time status of PH resources
- Syndromic Surveillance
  - o Improve early detection of emergent threats using EHR and other data sources
- Care plans and chronic disease burden management
  - o Improve capture and sharing of care plans, and coordination of chronic disease mgmt.
- Adverse Event Reporting
  - o Rationalize structures and improve capture of adverse events (e.g., vaccination reactions)
- Patient to device (mobile, med device) linking
  - o Better and easier linkages between mobile devices and person/patient enrolled to device
- Contact and Exposure Notification
  - o Investigate emerging tools/standards for contact tracing and exposure notification
- Vaccine credentials (AKA Vaccine Passport)
  - o The ISP TF has deferred to ONC's ongoing projects in this space

Arien directed HITAC members to the presentation materials where the ISP TF's framework for priority scoring and the results of the priority voting process were included on slides #7 and #8 and discussed the TF's process. **David** explained that the voting results were tabulated before the TF's receipt of expert opinions or other input, and he suggested that the TF might rescore the topics later. The results of the voting were (in order of highest to lowest ranking):

- Health Equity Standards – 24.67 points
- RWE/Comparative Effectiveness/RECOVERY EHR data use – 20.33 points
- Care plans and chronic disease burden management – 17.33 points
- Vaccine/Immunization Registry Reporting – 15.67 points
- Data sharing Federal & Commercial Health Care Entities – 15.33 points
- Clinical/Admin Data & Standards Harm/Burden Reduction – 14.33 points
- Syndromic Surveillance – 12.67 points

- Contact and Exposure Notification – 9.33 points
- PH Situational Awareness – 8.33 points
- Adverse Event Reporting – 8.00 points
- Patient to device (mobile, med device) linking – 5.33 points

David explained that the ISP TF has sought out expert input and has received several presentations. They are still working on scheduling additional informational sessions. He briefly described several of the expert presentations, which included:

- PH Situational Awareness
  - SANER (Audacious Inquiry) – April 1, 2021 TF meeting
- Health Equity
  - Bob Dieterle from Project Gravity (HL7) – April 8, 2021 TF meeting
- RWE / comparative effectiveness / Leverage EHR data
  - OHDSI, PCORI, COVID Cohort Collab – George Hripcsak, Chris Chute, Russ Waitman – April 16, 2021 TF meeting
- Data sharing across Federal and non-Federal boundaries
  - TBD?
- CDC Modernization
  - Paula Braun – CDC – April 29, 2021 TF meeting
- Clinical and Administrative data and standards prioritization
  - TBD (ICAD Task Force? DaVinci?)

David stated that the ISP TF would be willing to defer to the new HITAC task force on public health data systems to avoid conflict on overlapping work. Also, he directed members to the TF's presentation materials, which included an appendix of slides from expert presentations, and encouraged them to review the materials after the meeting.

Discussion:

- **Steven Lane** thanked the co-chairs for the presentation and stated that their work on the standards is foundational to the HITAC's ability to move interoperability forward.
- **James Ellzy** offered to provide contacts to the TF for presenters from the DoD/VA.

PUBLIC HEALTH DATA SYSTEMS

Micky Tripathi, National Coordinator for Health IT, ONC, presented a new Public Health Data Systems Task Force of the HITAC. He stated this is part of the work ONC is doing as a result of an executive order, and he is already co-leading a joint workgroup with Dan Jernigan of the CDC. The new task force will provide input in the future to the joint ONC/CDC workgroup.

The overarching charge of the new task force will be to inform HHS's response to President Biden's Executive Order on Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats. He stated that the specific charge is that the Public Health Data Systems Task Force shall:

- Identify and prioritize policy and technical gaps associated with the effectiveness, interoperability, and connectivity of information systems relevant to public health. This would include a focus on surveillance systems, infrastructure improvements, health equity, clinical engagement, long-term service and support systems, research and innovation, and empowering individuals.

- Identify characteristics of an optimal future state for information systems relevant to public health and their use.

Micky emphasized the importance of this work and encouraged HITAC members to volunteer to provide their expertise. Additionally, the task force may include members who are not on the HITAC. He asked if anyone had questions and reminded members that they should email the DFO, **Mike Berry**, at Michael.Berry@hhs.gov to express interest in participating and to indicate if they are interested in serving as a co-chair.

Discussion:

- **Denise Webb** asked **Micky** to share a potential timeline for the new task force.
- **Clem McDonald** stated that public health has been closed off in its activities over the years, so this is a nice change for them to try to connect. Also, he highlighted the potential problem of the separation of state and national public health systems and issues that might arise if/because data cannot flow smoothly (using different identifiers, etc.)
  - o **Micky** thanked **Clem** for his comments and acknowledged that public health systems are siloed. This new task force should work to move toward a public health ecosystem instead of a silo. He suggested that the project should have a further set of directional guidance related to technical and policy components.
- **Aaron Miri** inquired about the timeline for the new task force and its boundaries to mitigate future public health emergencies.
  - o **Micky** stated that there is some urgency around this because ONC is responding to an executive order. A public hearing will be held on May 13, 2021, and the task force should be launched by the end of April or early May. Recommendations should be completed by mid-July. Potential task force members should take this timeline into account. He suggested that the task force would look to be broad but practical in terms of its focus, work, and recommendations, and it will be future-oriented and will not be constrained by preconceived notions or old definitions of public health.
- **Mike Berry** noted that several people have already volunteered to serve as committee members. Others who are interested in serving should email Mike Berry as soon as possible.

General Discussion:

- **Les Lenert** asked about changes to public health operations and what they might mean for RWE coming into play in healthcare, especially in relation to the HIPAA rule and access to data for RWE. He also inquired if any proposed changes would impact data for public health operations.
  - o **Denise Webb** responded that the new task force could address these topics.
  - o **Aaron** responded that these questions would be addressed in the coming weeks with the NPRM being finalized and the new task force launch.
  - o **Les** reminded HITAC members of conversations held previously about interoperability issues related to health information exchanges (HIEs) and data from vaccination registries/test results. Commenters emphasized the need for regulations to support the rapid dissemination of vaccination status and test results through HIEs. He asked if the recently proposed updates to HIPAA would help remove barriers for research.

- o **Denise** asked **Les** to put these suggestions forth via the public comments process on the NPRM.
  - o **Aaron** stated the final HIPAA/OCR rule should clarify what constitutes an electronic signature as acceptable, as there are a variety of factors and laws that influence the answer.
- **Cynthia Fisher** submitted the following comments on the OCR presentation on HIPAA:
  - o The 15-day turnaround period for access to a patient's records is too long and should be shortened, possibly to real-time, given digital and technological advancements.
  - o She highlighted the importance of price transparency and including this information in the USCDI. Patients should have a right to information on billing through OCR because HIPAA states that they have the right to past, present, and future pricing and payment information.
  - o The HITAC should prioritize work on standards for billing to let consumers drive down healthcare prices by accessing standardized pricing information through the EHR before they receive care, not after.
  - o **Denise** emphasized the importance of a document that maps a crosswalk between the Cures Act/Information Blocking and the proposed updates to HIPAA in their new rule. She discussed the potential conflict between the definition in the Interoperability Provision around the Content and Manner Exception and OCR's proposed 15 day turnaround time.
  - o **Cynthia** stated that patients cannot access pricing information from hospitals without entering their individually identified and insurance information, making it difficult to privately and comparatively search for prices. The HIPAA should allow for immediate and easy access to this information. Also, she highlighted the issue of using the ICD-10 standard codes, which are a proprietary code by the American Medical Association (AMA), and price transparency parsers not being able to get access or responses to use the code to compare data on pricing. She suggested that AMA could be information blocking and stated that third-party apps for comparing healthcare prices across the market could be helpful. She also discussed the usefulness of an open source/non-proprietary standard for coding. The HITAC should focus on giving patients, consumers, and payers timely access to health information.
- **Steven Lane** responded to **Cynthia** that immediate digital access is the ultimate goal, but there are some categories of data that providers have not been comfortable providing immediately (including behavioral health notes or pediatric data) because they cannot assure that providing it might not meet an established exception for risk of harm and privacy. The provider might also need more time in certain situations to optimize the data released for a patient's needs.
  - o **Cynthia** responded that if the information is available to the healthcare provider in real-time in the medical record, it should be made available to the patient just as quickly. The standard of care has the potential to improve with digital access.
- **Carolyn Petersen** agreed that the proposed 15-day period, followed by an additional 15-day period at the discretion of the organization/provider, is excessive. However, she also agreed with **Steven** that there might be categories of data (mental health information, data about children who have been abused, etc.) that require additional review before release to ensure that the correct party(ies) receives the data. She proposed a 72-hour rule to create space for these processes while still ensuring rapid deployment of information to patients.
  - o **Aaron** added that similar discussions about not inadvertently harming a patient through the release of information were held during work on implementing the information blocking rule.

PUBLIC COMMENT

Mike opened the meeting for public comment. There was one public comment submitted by phone:

Nancy Spector, American Medical Association
Thank you. I'm speaking to the earlier report and recommendations by the USCDI task force. And the AMA has some significant concerns about the overlap between the current data class procedures and the proposed new data class for diagnostic studies and exams and even the new proposed data element for diagnostic imaging order. And there are several others who have posted comments on the USCDI website raising the same concern. The task force is recommending that there is a need to clarify the definition and scope of procedures due to its recommendation to add diagnostic studies/exams. But the problem is that procedures include diagnostic and therapeutic services. So, there is no real separation and distinction between procedures and diagnostic studies/exams. And even the terminology of diagnostic can be confusing because procedures can start out as diagnostic and then, change over to therapeutic.

For example, you can be having a diagnostic colonoscopy that can turn into therapeutic if polyps are identified and removed during that procedure. And there is the same when you have bronchoscopies and other scope procedures. There is that same dynamic. Another example can be a primary care physician doing a routine periodic screening EKG for a person over the age of 40. But in that same visit, if that patient happens to mention some recent episodes of chest pain then, that EKG becomes diagnostic and not just screening. So, we really do believe that adding the data class diagnostic studies/exams, no matter how it's intended to be used, will cause confusion for the classification of these data and the subsequent interpretation if they're exchanged among users. Thank you.

Clem McDonald commented in response to the public comment that HL7 distinguishes differences in the definitions of the procedures she mentioned, which can go from being a screening to diagnostic, depending on the circumstances of the visit. He agreed that this can create confusion, but he asked about the implications of not doing adding the data element.

Aaron stated that the HITAC could pose questions to a public commenter in writing outside the meeting.

Questions and Comments Received via Adobe Connect

Mike Berry (ONC): Good morning, and thank you for joining the April 2021 HITAC meeting. We will be getting started soon.

Clem McDonald: clem is here

James Ellzy, DoD: I'm here

Adi Gundlapalli (CDC): I am here too!

Amy Abernethy: Good morning.

Terrence O'Malley: I'm here, just lost audio

Amy Abernethy: I can hear but just can't talk yet. I am here and no COIs

Mike Berry (ONC): Welcome everyone!

Amy Abernethy: I am going to be cheering you on!

Andy Truscott: Thank you Amy!

Aaron Miri: Thank you Amy!!!
Robert Wah: Amy, great to have you on the HITAC. Regret that you were not with us when we had in person meetings. Best to you on your next adventure! Thanks!

Alexis Snyder: Welcome Steve!

Aaron Miri: Just to say Kudos to Dr. Lane and Leslie for their fantastic work and leadership guiding very lively and content rich conversations

Leslie Kelly Hall: Thank you Aaron!

Andy Truscott: You're very welcome sir.

michelle schreiber: agree with kudos to Dr Lane and Leslie for their leadership, and bringing consensus to the reccomendations - great presentations.

Jonathan Nebeker: Agree on the need for a clear framework on how USCDI fits into a larger picture.

Steven Waldren, MD: Moving from SNOMED CT to ICD 10 is NOT an advancement. Agree with recommendation, but the real issue is that billing is still done on ICD-10 not SNOMED CT.

Leslie Kelly Hall: @Steven W expand please

Steven Lane: Thank you Dr. Waldren.

Abigail Sears: What can do at the ONC or as part of the HITAC to help make the shift as a Country to SNOMED CT?

Andy Truscott: My personal view is that ICD 10 should be an interim step with SNOMED CT being the destination. Not sure how to use USCDI to do that.

Abigail Sears: What would the best approach be? I suspect people agree with SNOMED but how do we tackle the issue around billing

steve p (onc): Since ONC's 2012 certification rules for 2014 Edition and onward, SNOMED CT has been the only code system used for interoperability for "problems" -- since then it thus is how C-CDAs are required to be produced as well now for FHIR-based APIs.

Leslie Lenert: I think the issue is the time and effort for maintaining codes in an EHR. If providers need to learn one representation system for billing and a second for diagnosis, that adds a large amount of cognitive load.

Steven Lane: @Abby - Data holders are already required to include SNOMED. The TF is arguing that ICD-10, when present should also be included for access, exchange and use.

steve p (onc): For transitions of care, we have also required support for "encounter diagnosis" which could be coded using ICD-10

Leslie Lenert: Mapping is an alternative but mapping to a MORE expressive language is not straight forward.

Steven Lane: @SteveP - Yes! ICD is used for encounter diagnoses AND problems.

steve p (onc): "or's" become "and's" :)

Leslie Lenert: HPO? Human Phenotype Ontology?

Leslie Kelly Hall: True Stev P. but ICD is already pervasive. Most orgs doing concurrent coding are using ICD at the problem llist level

Leslie Lenert: it would be better to allow use of 1CD-10 than to have mapping that is done inconsistently across organizations to SNOMED

Nancy Spector: The AMA has concerns about overlaps between Procedures and the proposed new data class "Diagnostic Studies/Exams" and the proposed data element "Diagnostic Imaging Order." Procedures include diagnostic and therapeutic services and cannot be separately and distinctly defined from diagnostic studies/exams. Even the terminology of "diagnostic" may be confusing as procedures may start as diagnostic and change to therapeutic. For example, a screening/diagnostic colonoscopy can change to therapeutic if polyps are identified and removed during the procedure.

Jonathan Nebeker: For what it's worth. VA understands and agrees with the USCDI recommendation for ICD. There is still a need for a clearer picture of USCDI in regulatory and terminological domains into the future. The success of HHS in information blocking regs makes USCDI's role in the former domain less clear to a generalist like me.

Avinash Shanbhag: Clarification Question - Is the suggestion to require "SNOMED CT" and then allow ICD-10 as alternative (or optional)?

Jordan Hefcart: What sort of mechanisms does "unreasonable access control measures" include? IE, could 2-factor authentication ever be deemed "unreasonable' under the proposed language?

Jim Jirjis: Should there be a provision that ensures that photography is done in a context in which other patient's privacy is not compromised

Aaron Miri: @Jim - completely agreed.

Carolyn Petersen: What is right of access is proposed when a party that provides health care services (e.g., school, community facility such as a senior center) doesn't use an EHR?

Cynthia: 15 days length for a digital record when electronic records can be transmitted same day; we would never tolerate this in the financial services industry or anywhere else; getting these digital records now can be done same day which critical information will be lifesaving and provide substantially better quality care to inform patients and care teams with necessary health information

Mike: I believe he is talking about the HIPAA definition of EHR, and not "EHR"; as a type of software solution.

Brett Oliver, MD: Great question, Carolyn

Holly Miller, MD: +1 to Cynthia's comment. This is electronic exchange and should be near real time.

Aaron Miri: @Carolyn - great point. Or, as we identified clearly in our HITAC FACA - ealth IT for the Care Continuum Task Force; that there is state law in some places where elements of a record of mandated in hand written black ink. (e.g.: non electronic means)

Jim Jirjis: Shouldnt the shortening of the time frame from 30 to 15 days be timed to conincide with the 2023 EHI sharing capabilities? IT will be automated then

Susan Clark: State laws can be very inhibiting to exchange in many regards. They also have their own charging for copies prices that aren't always aligned with HIPAA.

Aaron Miri: @susan - Great point

Susan Clark: Case in point - just found out we can't send individually identifiable ambulance run reports to HIE until code is changed.

Aaron Miri: @Susan - yes. Or, vendors that provide patient portals, etc. that are conforming to IB rules and timelines and thus portions of the note or data elements are not available to release electronically until "2022" So... there's literally no mechanism to electronically auto release elements.

Adi Gundlapalli (CDC): @Aaron: wondering if release of laboratory results to patients is an example of auto-release. This does happen if the provider does not sign off of them in a reasonable time frame (has to be pre-specified). Thanks.

Steven Lane: @Adi - The InfoBlocking FAQs address this: https://www.healthit.gov/curesrule/resources/information-blocking-faqs

Steven Lane: See Q3 under EHI.

Mike: @Steven Lane - The information blocking FAQs are contradictory on this issue. Note the latest interference FAQ, which effectively necessitates auto-release prior to an actual request to avoid delays of any length should a request be in the form of an electronic query.

Steven Lane: Will this more extensive presentation be posted to the public web site? https://www.healthit.gov/hitac/events/health-it-advisory-committee-33

Brett Meeks: Understanding the need to navigate the CIOX decision, limiting the right to direct to a third party to just information from provider systems misses half the picture. If a patient asks their provider to track down their record under this new proposal, that provider should be able to ping plans as well as other providers to get as much of that patient's information as possible. Plans are covered entities as well and while they may not have electronic health records under the statutory definition, they retain plenty of electronic health information that will be required to be accessible through APIs under the CMS Patient Access and Interoperability rule.

Aaron Miri: @Brett - Yes exactly. Especially as if say the CE (e.g.: hospital) closes their doors, the plan may be the only place to retrieve a prior record

Brian Vamstad: Thank you Tim and team, excellent presentation! We look forward to submitting comments on the NPRM in the coming days.

Brian Vamstad: @Aaron Miri - ditto on a crosswalk to provide clarity with ONC regulations.

Carolyn Petersen: +1 for the crosswalk

Susan Clark: I think it would be safe to say +many on the crosswalk! I'm in.

Jim Jirjis: +1

Leslie Lenert: my question was ask Tim to discuss how changes impacted two areas: public health operations and research data sharing

Clem McDonald: Clem- I am back on too.

James Ellzy, DoD: I can provide DoD experts for "Data sharing across Federal and non-Federal Boundaries"

Jim Jirjis: Arien are you in a pantry?

Arien Malec: many thanks - very much appreciated

Susan Clark: Seeing the prioritization process was awesome. ANd I wondered if it was the garage?

Steven Lane: Sign me up!

Leslie Lenert: Good points Clem

Jonathan Nebeker: I know that you have started discussion in the Federal Coordinating Committee, which the Washington Post reported on. Are you looking for members from the government to serve on this new task force to help bridge the two groups and explicitly help coordinate?

steve p (onc): Hi, Jonahthan N, this is different than the vaccination verification/status reported on by press

Jonathan Nebeker: Right.

Steven Lane: Steve - It would seem that vaccination verification/status would be included in the scope of the discussion of the new TF even if they are not tasked with providing input on this specifically.

Mike Berry (ONC): We will open the line for public comments soon. To make a comment please call:1-877-407-7192 (once connected, press "*1" to speak).

Steven Lane: I was dropped from the call. Dialing back in.

Sheryl Turney: A crosswalk would be very useful to consumers to help them understand how all of these rules work together

Steven Lane: Back on.

Robert Wah: @Cynthia ICD-10 is not from the AMA

Leslie Lenert: Great point on pricing: We need a standard for publishing pricing data in electronic form. Lack of these standards is allowing providers to obfuscate their prices.

Leslie Lenert: Maybe we could addthis to the ISP task force agenda?

Micky Tripathi 2: Thank you Aaron and Denise, and to the entire HITAC!

David McCallie: @Leslie +1

FINAL REMARKS

Mike reminded members that the next meeting of the HITAC will take place on May 13, 2021, and noted that the Public Health Data Systems hearing would be included in that meeting. HITAC members should expect a longer length meeting.

Aaron highlighted the growing vaccination numbers, thanked providers for their efforts during the pandemic, and asked HITAC members to prioritize mental health as a public health item of note in the HITAC's future work.

Denise and **Aaron** thanked the presenters for their thoughtful comments and participation and ONC and Accel for their support. **Denise** reminded everyone they have until May 6, 2021, to submit comments on the proposed HIPAA rule changes. **Aaron** encouraged all eligible members to get vaccinated and to emphasize health equity at their organizations.

ADJOURN

The meeting was adjourned at 2:00 p.m. ET.